neuroKINESIS CORPORATION

10524 South La Cienaga Blvd.
Los Angeles, Ca 90304
Tel: 310-649-9000
Email: info@neuro-kinesis.com
Website: neuro-kinesis.com

FOR IMMEDIATE RELEASE

NKC Announces Upcoming Animal Study for Clinical Validation of its Huygens™ – Proteus™ Robotic Arm Surgical Platform

August 30, 2022 | News

Multi-center trials to commence Q1 2023 at Technion and Sandia

Neuro-Kinesis Corp. (NKC) has submitted an Application for an Institutional Animal Care and Use Committee Approval (IACUC) for its upcoming animal studies of the **Huygens™ – Proteus™ Robotic Arm Surgical Platform**. An agreement has been signed with the **Technion Institute** in Israel to begin the animal study validation of **NKC's** surgical platform in Q1 2023. The platform includes the **Huygens™ Catheter**, the **Lorentz™ Active Sheath**, and the **Proteus™ Robotic Arm** which have been in development over the last several years.

The study will be headed by **NKC** Chief Electrophysiology Officer, Dr. Eli S. Gang, MD (Clinical Professor of Medicine, Geffen School of Medicine at UCLA, Cedars Sinai Medical Center). The study will be performed under the guidance of Principal Investigator Dr. Rona Shofty, DVM, PhD, DLAM.


Dr. Eli Gang

The study as shown will demonstrate the ability of the **Huygens Catheter** to generate clinical data that is superior to the existing art, thereby demonstrating improved clinical indices in electrophysiological therapeutic procedures. Specifically the study is designed to demonstrate the ability of the **Huygens™ Catheter** to perform detailed mapping and target acquisition procedures in all four chambers of the test subject's heart. Success in this study will constitute proof-of-design adequacy and equipment safety in reaching the efficacy and safety goals established in the study protocols.

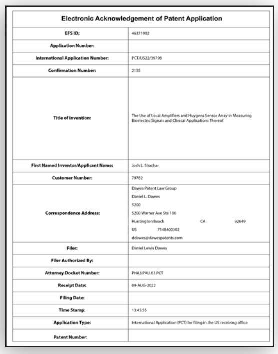
A separate agreement is being finalized with **Sandia National Laboratories** to perform real-time simulation studies of the system under the guidance of Dr. Darren W. Branch, PhD., and is anticipated to proceed concurrently to demonstrate the embodiments that differentiate the **Huygens™ Catheter** from any other catheter in the marketplace today.

System Integration to be done at NKC Headquarters

In anticipation of the application's approval, **NKC** expects to have installation of its **Huygens-Proteus Robotic Arm Surgical Platform** completed at its lab facility in Los Angeles, California by the end of October. Once completed, **NKC** will begin its own internal validation studies in preparation for the above trials.

The lab installation will allow the **NKC** engineering team the ability to test prototype designs, perform quality control checks, and establish operational and test protocols while gathering the important analytical and comparative clinical data needed to further its regulatory approval strategy.

New NKC Patent Filing



Electronic Acknowledgement of Patent Application	
EFS ID:	46371902
Application Number:	
International Application Number:	PCT/US22/39798
Confirmation Number:	2155
Title of Invention:	The Use of Local Amplifiers and Huygens Sensor Array in Measuring Bioelectric Signals and Clinical Applications Thereof
First Named Inventor/Applicant Name:	Josh L. Shachar
Customer Number:	79782
Correspondence Address:	Dawes Patent Law Group Daniel L. Dawes 5200 5200 Warner Ave Ste 106 Huntington Beach CA 92649 US 7148400302 ddawes@dawespatents.com
Filer:	Daniel Lewis Dawes
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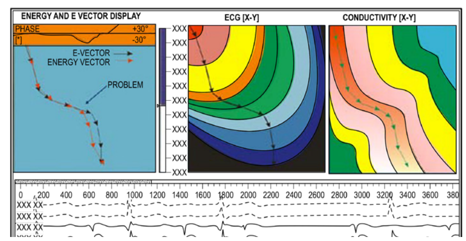
Attorney Docket Number:	PHA3.PAU.63.PCT
Receipt Date:	09-AUG-2022
Filing Date:	
Time Stamp:	13:45:55
Application Type:	International Application (PCT) for filing in the US receiving office
Patent Number:	

NKC has filed a new patent application developed by **NKC's** CTO Josh Shachar. Titled, *"The Use of Local Amplifiers and a Huygens Sensor Array in Measuring Bioelectric Signals and Clinical Applications Thereof"* (PCT/US2022/030399), the patent relates to the field of electrophysiological mapping methods using the **Huygens™ Catheter** with its capabilities of co-measuring impedance and local native biometric signals, and employing such signals with a method that identify a "phase singularity" within the electroanatomical space as well as its dynamics.

Clinically, this means the **Huygens™ Catheter** might solve one of the most fundamental problems in electrophysiology, and can then be used as a standard tool for care in treating pacing problems such as A-Fib and other disease models.

To date, **NKC** has filed eight patents, both domestically and internationally, describing its advanced catheter technology. This is in addition to the more than 30 patents and patent applications **NKC** has already filed in its IP strategy to both define and protect the company's growing advanced medical technology platforms.



One of the advances enumerated in the patent, is the ability of the **Huygens™ Catheter** to accurately identify and measure phase singularities in order to provide a more accurate representation of the bioelectrical activity in the heart chamber.

General Integration of NKC Platform with Abbott/St. Jude EnSite NavX System

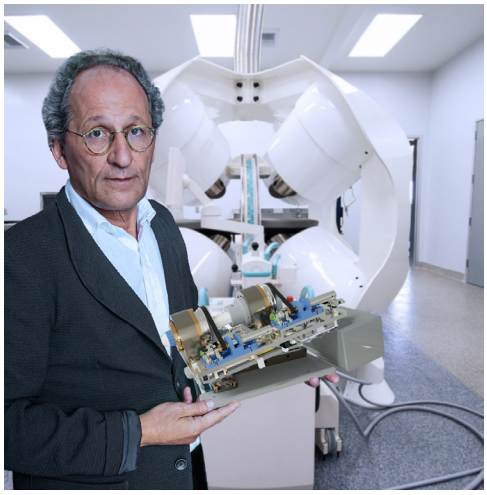
Abbott/St. Jude EnSite NavX
EP Mapping System

NKC has entered into a collaboration with Abbott/St. Jude to integrate its **Huygens™ - Proteus™ Surgical Platform** with their industry-standard EnSite NavX EP mapping system, allowing data collected by the **Huygens™ Catheter's** sensors to seamlessly integrate with the mapping system to create anatomical maps with dynamic range and resolution exceeding current standards; a parameter which will be qualified by **NKC's** upcoming animal studies. The use of the EnSite NavX system with the **Huygens™ - Proteus™ Surgical Platform** will create faster high-density maps of any cardiac chamber while also providing the EP Surgeon information about the best diagnostic and ablation catheters to meet the need of the patient.

From 9 Ton to 9Kg

The **Huygens™ – Proteus™ Surgical Platform** represents two decades of work in advancing robotic catheter guidance from its original 9-ton flagship **CGCI (Catheter Guidance Control & Imaging) Robotic System** down to the 9kg device it is today.

CGCI was one of the first catheter guidance systems that used magnetic fields to navigate a specially designed catheter through a living heart chamber to provide interior tissue mapping for cardiac ablation procedures. The system utilized remote navigation using robotic control and artificial intelligence to maneuver the catheter tip exactly where the EP surgeon wanted. The system also integrated autonomous guidance for the ability to return a catheter automatically to a pre-mapped and targeted position.



CTO and Inventor Josh Shachar showing comparison of the **9kg** Proteus™ Robotic Arm next to the **9 ton** CGCI..

The advances made with **CGCI**, and its early-development prototype, the **MOSFET Catheter** counterpart, have paved the way for the **Huygens™ Catheter** and the **Proteus™ Robotic Arm,** reducing the technology that required a dedicated operating suite into a portable, plug-and-play system that can be deployed into any existing EP operating room while delivering detection sensitivity, mapping resolutions and AI enhanced guidance that can dramatically change the face of EP cardiac diagnostics and treatment.

Addition of Seasoned Regulatory Expertise to NKC Team

NKC has contracted two new team members to navigate the FDA regulatory pathway for product approval of the **Huygens™ Catheter** and the **Proteus™ Robotic Arm** technologies: Prof. Elaine Duncan (Paladin Medical Inc.) and Dr. Jaap Laufer MD (Emergo Group Inc. Both of these highly qualified individuals bring to the table decades of experience in successfully guiding groundbreaking medical technologies to market.

Prof. Elaine Duncan

Professor Duncan is the founder and president of Paladin Medical®, Inc. and is a certified regulatory affairs professional with a master's degree in engineering. She holds an appointment as an Adjunct Professor of Biomedical Engineering in the F. Joseph Halcomb III, M.D. Department of Biomedical Engineering at the University of Kentucky and is a recognized leader in regulatory/clinical strategies for new medical technology development.

Dr. Jaap Laufer MD

Dr. Laufer has over 30 years of regulatory and clinical experience specializing in implant, high-risk device and combination product submissions, FDA QSR compliance, and clinical study submissions and compliance. He has held corporate positions in Regulatory and Clinical Affairs for the Switzerland–based Lipomatrix, Pfizer Hospital Products Europe, and global giant Abbott Laboratories.

Dr. Susan Alpert

Together, along with Lead Regulatory Consultant, Susan Alpert MD, who has 30 years of experience and was the former Senior Vice President of Global Regulatory Affairs, at Medtronic, and Quality Engineer Elissa Salceda, who has been hands-on in the development of the **Huygens™ – Proteus™ Robot Arm Surgical Suite**, the **NKC** regulatory team is on a solid path forward to achieving its first major commercialization milestone, FDA approval. This milestone will allow entry of the **NKC** technology into the U.S. marketplace. This will also provide benchmark clearance for the European CE Mark.

Elissa Salceda

Anacaz Group to Develop Digital Backend for NKC Clinical Data Management

NKC is in negotiations with Anacaz Networks Inc., to support the development of cloud-based operations and ensure the security and safety of the preserved patient data acquired with the **Huygens™ – Proteus™ Surgical Platform**. This data will allow physicians to review the exact conditions and events recorded during a procedure including placement of ablative lesions, rotor locations, and the complete replay of actions taken by the surgeon. The establishment of this dedicated secure cloud platform will provide the ability for patient information and treatment to be accessible to the patient designated healthcare providers as well as creating a growing database of information to be available for expanding the knowledge base of cardio-disease treatment for EP physicians everywhere. Creating this secure central share-point is in alignment with **NKC's** vision of helping to improve the EP art, and to democratize medicine for everyone.

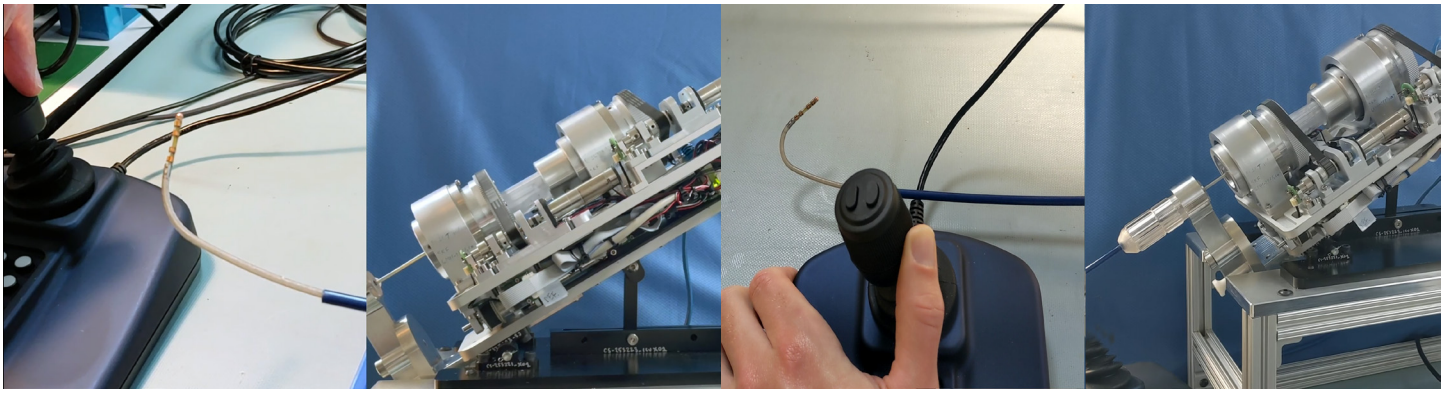
Rob Abrams

Anacaz Networks is the recognized leader in high speed L4-L7 packet processing. The company was founded by Robert Abrams who has 30 years of experience and was central in providing many high-tech innovations including the Veritas High-Performance File System, Cisco Catalyst 5000, Cisco PIX Firewall, SonicWALL Cyber Security Solutions, Apple iMac Pro and MBP, and the AMDI Labs AutoLab Antibody line of test solutions. He has worked with major tech industry players such as Cisco, Apple, Fujitsu, Sony, Samsung, Broadcom, as well as many other Fortune 500 companies.

about NKC

Neuro-Kinesis Corporation is a medical technology company focused on creating next-generation surgical tools incorporating advanced biosensor systems that can provide real-time biofeedback of a variety of process critical data to a physician or surgeon where the monitoring of precise environmental status points can greatly enhance a patient's procedural outcome.

Interest in the **NKC** surgical tool technology has already been generated in several large medical device companies, and the company is on track to complete the continued prototyping and research studies required to bring their initial product candidates to pre-market commercialization.



The images above show the **Huygens™ – Proteus™ Robotic Arm Surgical Platform** in development trials at **NKC.** From the left, the first two images show the **Huygens™ Catheter** being "steered" by the **Proteus™ Robotic Arm**. The **Proteus™** is capable of moving the catheter in five degrees of freedom in any of the endocardial spaces. The third images shows a prototype joystick allowing effortless navigation control of the catheter by the EP surgeon. The final picture shows the **Proteus™ Robotic Arm** and part of the **Proteus™ Catheter Handle** being tested to confirm full rotational, transitional and deflection movement control. The above constitutes the full system.

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